IV. Conduct of inspections:

A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

A. Sampling and analysis.
B. Recall monitoring.
C. Product defect reporting system.
D. Routine surveillance inspections.
E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

APPENDIX E TO SUBPART A OF PART 26—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM

1. Documentation

—Definition of a crisis/emergency and under what circumstances an alert is required
—Standard Operating Procedures (SOP's)
—Mechanism of health hazards evaluation and classification
—Language of communication and transmission of information

2. Crisis Management System

—Crisis analysis and communication mechanisms
—Establishment of contact points
—Reporting mechanisms

3. Enforcement Procedures

—Followup mechanisms
—Corrective action procedures

4. Quality Assurance System

—Pharmacovigilance programme
—Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44–171–418 8400, Fax 418–8416.

B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301–827–6190, fax: 301–594-1944.
Human Drugs: Director, Office of Compliance (HFD–300), MPN I, 7520 Standish Pl., Rockville, MD 20855–2737, phone: 301–594–0054, fax: 301–594–2114.
Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

Subpart B—Specific Sector Provisions for Medical Devices

§ 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the

other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

§ 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

§ 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in Appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

§ 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in Appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

§ 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

§ 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other party a list of CAB's which meet the criteria for technical competence and